

REMARKS

This application currently stands abandoned. Submitted herewith is a petition under 37 CFR 1.137(b) for revival of an unintentionally abandoned application. The amendments filed herewith are in response to a first office action rejection dated February 4, 2009. In view of the amendments and remarks provided herein, reconsideration and withdrawal of the rejection is respectfully requested.

The Examiner has withdrawn the rejections of the previous office action, dated September 10, 2007. Specifically, the rejection under 35 USC Sec. 103 for alleged obviousness over O'Connor (US 6,029,659) in view of Rand (US 6,431,168) has been withdrawn.

Upon revival of the application, claims 1-6, 10-15, 45-48, and 55-56 are pending. Claims 1 and 56 have been amended. Claims 13 and 47-48 have been canceled, and new claim 57 has been added. Support for the amendments and new claim 57 can be found at various places in the specification including, for example, at paragraphs 52, 62-63, and 77-80, and in Figures 8 and 21-23 of the published application.

Applicants assert that no new matter has been introduced by these amendments.

Rejection Under 35 U.S.C. §102

Claims 1-6, 10-15, 45-46, and 55-56 stand rejected under 35 USC Section 102(b) for alleged anticipation over US 5,284,133 (hereinafter "Burns"). Burns teaches an inhalation device such as an MDI having an actuator that prevents actuation of the device at non-prescribed intervals and/or at higher than prescribed doses, which aids in patient compliance with prescribed treatment regimens. The Burns device incorporates a locking mechanism and programmable control unit that locks up the device to prevent actuation at inappropriate times.

In order to anticipate, a single reference must disclose, expressly or inherently, each element of the claimed invention. In re Bond, 15 USPQ2d 1566 (Fed. Cir. 1990).

According to the rejection, Burns anticipates claim 1 by allegedly disclosing, among other elements, "a ramp 44 that is contacted by a ferrule portion of the canister in a direction substantially non-axial to the first direction . . . and a seal isolating the counter

from the mouthpiece and the canister to prevent contamination.” The rejection further states, “The guide tube 12 and the cover of the controller is defined as the seal; see figures 4A and 4B; col. 10 lines 5-20.” Applicants respectfully traverse.

Without conceding the basis for this aspect of the rejection, and solely in the interest of advancing prosecution, Applicants have amended claims 1 and 56 and added new claim 57 to include the element “canister holder” and to clarify that the seal element renders the counter substantially water-resistant, and that the seal comprises a ramp.

Regarding claim 1, Applicants respectfully argue that Burns fails to expressly or inherently teach each element of the claim. First, Burns does not teach a device having a seal that isolates the counter from the mouthpiece and canister to prevent contamination. As claimed, the seal element of the present invention isolates the counter from the rest of the device and prevents cross-contamination between the counter and inhalation airflow path. It also renders the counter module water-resistant. Burns does not expressly or inherently teach a seal. While the rejection states that the guide tube 12 of Burns “is defined as the seal” there is no substantive basis for this assertion in Burns *per se*, nor has a reasoned argument been offered in support. The citations provided in the rejection to certain sections of the Burns specification, namely figures 4A and 4B, and at Col 10, lines 5-20 do not clearly and unambiguously teach a seal, let alone that the guide tube functions as a seal.

On the contrary, the disclosure of Burns teaches a guide tube that serves as a holder or housing for a canister, and nothing more. Indeed, Fig 4A of Burns undermines this assertion by showing that the guide tube is not sealed, nor does the guide tube provide a sealing function, to itself or to any other component part of the device (see feature 22 of Fig 4A, which is an air inlet port; also shown in Fig 1). Indeed as revealed in Figs 1 and 4A of Burns, full and open communication exists between the counter of Burns and the airflow path.

At least a second reason that Burns does not anticipate is that it does not teach a seal that comprises a ramp. Even if the guide tube were to be construed to be a seal, which, as elaborated in the preceding paragraphs, Applicants dispute, Burns would still not anticipate claim 1, since the guide tube does not comprise a ramp. Indeed, as taught in

Burns, the lever that contacts the ferrule portion of the canister (referred to as a “ramp” in the rejection) is a part of the controller, not the canister holder (Fig 4A, Col 10, lines 7-19).

As such, Burns does not anticipate claim 1, or any claims dependent therefrom. For similar reasons, Burns does not anticipate claim 56. Withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. §103

Claims 47 and 48 were rejected allegedly as being obvious over Burns. Without conceding the basis for this aspect of the rejection, Applicants have canceled claims 47-48 while reserving the right to later claim this subject matter. As such this aspect of the rejection is rendered moot. Applicants respectfully request withdrawal of this aspect of the rejection.

CONCLUSION

In view of the amendments and the foregoing remarks, it is respectfully requested that the rejection set forth in the Office Action dated February 4, 2009 be withdrawn and that this application be passed to issuance as soon as possible.

Respectfully submitted,

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